Intermediate Products for Technical Use in Medical Devices, In Vitro Diagnostics, or Laboratory Materials

The European Union published Regulation (EC) 2007/2006 on December 22, 2006. This regulation amends Regulation (EC) 1774/2002 to allow certain intermediate products to be imported into the EU.

The exporter is responsible for having their importer confirm prior to export that shipments will be allowed entry under Regulation (EC) 2007/2006.

Shipments that are eligible to enter the EU as intermediate products require no government endorsed certificate. Shipments must be accompanied by a declaration for the importation from third countries and for the transit through the European Community of intermediate products to be used for medical devices, in vitro diagnostics and laboratory reagents" endorsed by the European importer. The model declaration published by the EU is included at the end of this document.

The declaration must be in at least one of the official languages of the EU Member State in which the inspection at the border inspection port is carried out and of the EU Member State of destination.

The EU regulation defines "intermediate product" as *"a product derived from Category 3 material intended for the manufacture of medical devices, in vitro diagnostics or laboratory reagents, and whose design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as processed products and to qualify the material for that purpose, except for the fact that it requires some further handling or transformation such as mixing, coating, assembling, packaging or labeling to make it suitable for placing on the market or putting into service in accordance with the Community legislation applicable to the final products concerned."*

In order for items to be exported to the EU as intermediate products, they must:

- Be composed entirely of Category 3 material sourced from approved suppliers;
- Be processed in some way;
- Be exported directly to approved facilities in the EU for further handling or transformation such as mixing, coating, assembling, packaging or labeling prior to placing on the market or putting into service **in Medical Devices, In Vitro Diagnostics, or Laboratory Material**;
- Not be derived in any way from equidae blood (e.g. horse serum);
- Not be raw blood from any species, raw milk, hides and skins of ungulates, pig bristles, wool, hair, feathers or parts of feathers; and
- Be accompanied when imported to the EU by a "declaration for the importation from third countries and for the transit through the European Community of intermediate products to be used for medical devices, in vitro diagnostics and laboratory reagents" endorsed by the European importer.

Prior to exporting products to the EU as intermediate products, exporting facilities must be approved by APHIS as Intermediate Facilities. Please contact your local APHIS Veterinary Services Area Office for information on how to obtain this approval.

All facilities currently approved by APHIS Veterinary Services as Regulation (EC) 1774/2002 Technical Blood (Non-Equidae) Facilities will automatically be placed on the list of approved Regulation (EC) 1774/2002 Intermediate Product facilities.

Prior to seeking this approval or exporting materials as intermediate products, the exporting facility **must have their European importer or importers confirm with the Ministry of Animal Health in the importing EU Member State that the specific products to be exported will be permitted entry into the country accompanied by only the above referenced importer declaration.** There are likely to be significant variations in which Member States allow which materials to be imported under these requirements. If government (APHIS) certification of shipments is required, then shipments may not be exported as intermediate products.

NOTE- Not all Category 3 Materials may be exported to the EU as Intermediate Products.

ANNEX II

Model declaration for the importation from third countries and for the transit through the European Community of intermediate products to be used for medical devices, in vitro diagnostics and laboratory reagents

COUNTRY **Model declaration**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Tel. No		I.2. Document reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the consignment in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU	
		I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for: Technical use ☐ Other ☐			
I.26. For transit to 3rd Country vis-à-vis EU ☐ 3rd country ISO code		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Approval number of establishments Manufacturing plant	Net weight	Batch number

MODEL DECLARATION FOR INTERMEDIATE PRODUCTS TO BE USED FOR MEDICAL DEVICES, IN VITRO DIAGNOSTICS AND LABORATORY REAGENTS, FOR DISPATCH TO OR FOR TRANSIT THROUGH THE EUROPEAN COMMUNITY

I, the undersigned, declare that the intermediate products referred to above are intended to be imported by me into the Community and that:

1. they are derived from Category 3 material referred to in Article 6 of Regulation (EC) No 1774/2002 [1] and are intended for the manufacture of medical devices, in vitro diagnostics or laboratory reagents;
2. their design, transformation and manufacturing stages have been sufficiently completed in order to be regarded as processed products and to qualify them for that purpose, except for the fact that they require some further handling or transformation such as mixing, coating, assembling, packaging or labelling to make them suitable for placing on the market or putting into service in accordance with the Community legislation applicable to the final products concerned;
3. their outer packaging is labelled 'FOR MEDICAL DEVICES/IN VITRO DIAGNOSTICS/LABORATORY REAGENTS ONLY'; and
4. they will not be diverted at any stage within the Community for any use in food, feed material, organic fertilisers or soil improvers and will be conveyed directly to the following establishment:

Name: ..... Address: .....

The importer

Name: ..... Address: .....

Done at: .....
(place) *(date)*

Signature: .....

---

[1] List of Category 3 materials (referred to in Regulation (EC) No 1774/2002 (OJ L 273, 10.10.2002, p. 1):
(a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons,
(b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation,
(c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that were slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,
(d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation,
(e) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves,
(f) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals,
(g) milk originating from animals which do not show any clinical signs of any disease communicable through that product to humans or animals,
(h) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production,
(i) by-products from fish from plants manufacturing fish products for human consumption,
(j) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals.